

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)	1. CERTIFICATE NUMBER: 93-R-0433 CUSTOMER NUMBER: 9192	FORM APPROVED OMB NO. 0579-0036
University Of California, Davis One Shields Ave Davis, CA 95616 Telephone: (530) -752-2364		
3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)		

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)					
A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs		280	690		970
5. Cats		831	353		1184
6. Guinea Pigs		28	128		156
7. Hamsters		56	200		256
8. Rabbits		282	270		552
9. Non-human Primates	3486	106	2743		2849
10. Sheep		271	376		647
11. Pigs		853	147		1000
12. Other Farm Animals					
Cattle		1476	915		2391
13. Other Animals					
Alpaca		1			1
Dolphin		24			24
Donkey		1			1

ASSURANCE STATEMENTS 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research teaching, testing, surgery, or experimentation were followed by this research facility. 2) Each principal investigator has considered alternatives to painful procedures. 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected. 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL (Chief Executive Officer or Legally Responsible Institutional Official)	
SIGNATURE	<div style="background-color: black; width: 100%; height: 40px; margin-bottom: 5px;"></div> <div style="text-align: center; margin-bottom: 5px;">b6, b7c</div> <div style="text-align: right; margin-top: 10px;"> DATE SIGNED 11/29/06 </div>

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

CUSTOMER NO.

93-R-0433

9192

FORM APPROVED
OMB NO. 0579-0038

**CONTINUATION SHEET FOR ANNUAL REPORT
OF RESEARCH FACILITY**
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

University of California, Davis
One Shields Ave.
Davis, CA 95616

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use this form.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
Ferret		7	20		27
Fox		33	64		97
Goat		201	332		533
Horse		150	560		710
Llama		3			3
Wild Rat			93		93
Squirrel		20	209	30	259
Vole		120	608		728
Whale		14			14
Opposum			20		20
Badger			9		9
Deer			6		6
Deer mouse			245		245
Gerbil			100		100
Skunk			40		40
Wild mouse			364		364
Chipmunk			14		14
Wild Rabbit				200	200

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGN

b6, b7c

DATE SIGNED

11-29-06

APHIS FORM 7023A
(AUG 91)

(Replaces AF Form 10-62 (01-69), which is obsolete)

HEADQUARTERS

Attachment 1B

EXPLANATION FOR COLUMN E LISTING

(This report must accompany USDA VS APHIS Form 7023(Aug. 91) to support Column E Listing.)

ICD: **Customer ID 9192** **Registration Number 93-R-0433**

Animal Study Proposal Title: Ground Squirrel Underground Baiting

Number and Species of Animals Listed in Column E.

Species: California Ground Squirrel **Number: 30**

Brief description of project including reason(s) for species selection:

This project is designed to identify the factors in squirrel behavior and feeding habits that prevent the successful use of underground baiting alternatives such as in-burrow baiting and underground bait stations, and to further optimize timing of bait application for squirrel population reduction. Grain treated with two different anticoagulants will each be placed in an experimental underground bait station, a traditional inverted-T bait station, as well as in-burrow baiting to determine comparative usage and effectiveness in reducing squirrel populations.

Squirrels are studied because they are economically important crop pests. Squirrels also frequently inhabit the same locations as humans and thus are in close proximity to them, and are vectors for pathogens that pose a risk to public health. Both farmers and environmental health workers are interested in finding more effective methods for controlling populations of ground squirrels to reduce crop damage and health risks. This study seeks to help define the most efficient manner in which to target squirrels and at the same time reduce non-target and other unintended consequences of using anticoagulant rodenticides when such use is necessary.

Justification for unrelieved pain or distress:

The animals will not be euthanized as the study must determine the comparative effectiveness of two anticoagulants in reducing squirrel population under different field baiting conditions. Squirrels may not consume an effective amount of bait under certain field baiting conditions resulting in a moribund appearing animal which may recover instead of succumbing to the toxic effects of the bait. Early euthanasia would negate the purpose of the study.

Please see attached e-mail from Dr. William Jacobs, primary efficacy data reviewer for the vertebrate pesticides at the EPA. This e-mail, and subsequent communications with Dr. Jacobs on 10/31/05 and 9/25/06, verifies that for rodenticide studies, death is the response that must be assessed.

Attachment 1B

EXPLANATION FOR COLUMN E LISTING

(This report must accompany USDA VS APHIS Form 7023(Aug. 91) to support Column E Listing.)

ICD: **Customer ID 9192** **Registration Number 93-R-0433**

Animal Study Proposal Title: A field test of jackrabbit bait station strategies

Number and Species of Animals Listed in Column E:

Species: Black-tailed Jackrabbit **Number: 200**

Brief description of project including reason(s) for species selection:

Jackrabbits are pests of a variety of crops, but controlling them using bait stations is of concern to the U.S. Environmental Protection Agency because of the potential for bird species to consume the bait. We identified a bait station design that inhibits bird use, but the best baiting strategy (e.g. pre-baiting or not) and the effectiveness of anticoagulant baiting on controlling jackrabbit populations must still be determined.

The objectives for this study are to: 1) Determine if it is necessary to pre-bait and “train” jackrabbits to enter A-frame bait stations prior to offering anticoagulant bait, and 2) Determine if effective control can be achieved by deploying the bait stations, bypassing any pre-baiting period.

Justification for unrelieved pain or distress:

Because rodenticides are being tested, it is important to determine whether the animal will recover. Early euthanasia would negate the primary measure of the evaluation of the baiting strategy.

Please see attached email from Dr. William Jacobs, primary efficacy data reviewer for vertebrate pesticides at the EPA. This e-mail, and subsequent communications with Dr. Jacobs on 10/31/06 and 9/25/06, verifies that for these studies, death is the response that must be assessed.

**University of California, Davis
Annual Report of Research Facility
USDA Reporting Year 2005**

Email from Dr. Jacobs of the Environmental Protection Agency: Justification of Category E rodenticide studies. This e-mail, and subsequent communications with Dr. Jacobs on 10/31/05 (telephone conversation) and on 9/25/06 (email), verifies that for rodenticide studies, death is the response that must be assessed.

-----Original Message-----

From: Jacobs.Bill@epamail.epa.gov [mailto:Jacobs.Bill@epamail.epa.gov]
Sent: Monday, September 25, 2006 6:53 AM

b6, b7c

Subject: Re: Rodenticide testing at UC Davis

I stand behind the thoughts expressed in my e-mail message of July 12, 2004, regarding rodenticide testing at UC Davis. I have nothing of significance to add to the statements in that message at this time. Note that that message was a direct response to an inquiry made directly to me.

From: Jacobs.Bill@epamail.epa.gov
Sent: Monday, July 12, 2004 9:36 AM
To: Lon Kendall
Subject: Re: rodenticide testing UC Davis

I am William W. Jacobs, Jr., Ph.D. I have been EPA's primary efficacy data reviewer for vertebrate pesticides for the past 26 years.

In relevant part, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) defines "pesticide" as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest". Vertebrate pesticides are used to exert such effects on vertebrate animals which have been determined to be pests. Vertebrate pesticides include: (1) products which are claimed to prevent, repel or otherwise mitigate vertebrate pests, and (2) products which are claimed to kill (destroy) vertebrate pests. Most of the toxic rodenticides are applied as baits. For both poisons and repellents, targeted animals' sensory and physiological responses are important factors affecting whether products work as claimed. Consequently, efficacy studies of vertebrate pesticide products are essentially behavioral studies in which animals responses to the products are observed (directly or indirectly) and any physiological effects attributable to the product are noted.

With repellents, an observation consistent with repellency may be attributed to sensory effects (e.g., offensive odor, trigeminal irritant, etc.) or to sensory effects coupled with internal effects (perception of flavor followed by illness leading to a conditioned food aversion). In both cases, the experiment may be continued because it is often essential to determine the duration of the behavioral effect so that product labeling can tell users how long they can expect the product's effects to last.

For tests of products claimed to kill vertebrate pests, death is the response that must be assessed as it is the endpoint claimed on the label and desired by the user. In efficacy studies involving rodenticide toxicants, it is

fundamental that observations of animals continue until the animal succumbs completely to the poison (i.e., dies) or recovers. (Death and recovery are behavioral responses which reflect physiological circumstances.) The entire point of using toxic rodenticides is to kill targeted animals. Put another way, if the product does not kill animals, it is not worth using. If the product is worth using and is registered, it will kill many times more animals in operational use than it does in research.

Efficacy research should continue until the relevant research questions are answered. In studies with toxic rodenticides, the researcher must determine the level of efficacy obtained. In laboratory trials, this involves the proportion of animals that the rodenticide kills. Animals that become symptomatic may, if the study continues, die or recover. Animals that die contribute to establishing the level of efficacy and also provide information about the amount of bait taken, the course of symptoms leading to fatality, the pathology of fatally poisoned animals, and the residue levels in fatally poisoned animals. Were such animals sacrificed prematurely, the information on bait ingestion, symptomology, pathology, and residue levels would have no proper context because it would not be known whether the results pertained to a (likely) victim or a (likely) survivor.

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Animals that survive rodenticide laboratory experiments also are of great interest. If an animal survives, the researcher (or reviewer, in my case) should attempt to learn as much as possible from the animal because, in the real world of rodenticide use, it is the survivors who become the ancestors of the rebounding pest population. How much bait each survivor ate may suggest why it survived. A survivor that ate little bait may have not have ingested enough poison to kill it. If the survivor rejected bait in favor of challenge diet throughout the bait-exposure period, that would suggest that the animal did not find the bait to be palatable. Presenting the same poison in a different bait might lick that problem, unless the poison itself is what made the bait unpalatable. If the animal ate some bait on the first day and none thereafter, that would suggest that the animal had ingested a "symptomatic" amount, associated the physiological effect with the flavor of the bait, and developed a conditioned food aversion ("bait shyness" in rodenticide parlance). Bait-shy animals typically cannot be controlled with a bait having a flavor similar to the one that they learned to avoid.

All of this behavioral information would be lost if, for example, subjects were to be "humanely sacrificed" at the sign of the first symptom. (In what strikes me as utter "scientific" folly, the UK actually requires that rodents in choice feeding trials with anticoagulants be sacrificed 4 days into the test, by which time there would be few toxicant-caused deaths and only very general symptoms suggesting toxicosis. Under such a procedure, more information is arbitrarily discarded than is collected. So the researcher knows how much bait and how much challenge diet was ingested. The researcher does not know the effects of such ingestion, so what was the point in measuring it?)

In field efficacy trials, product performance is assessed through estimating the effects of treatment on the targeted population. As not all members of the population will (or can) be seen prior to treatment, usually indirect and/or sampling indices to animal activity are used rather than counts of all individuals. The carcasses of most victims usually will not be observed. As target species are likely to be at least semi-fossorial, deaths often will occur above ground. Symptomatic animals observed above ground should be allowed to succumb or recover so that estimates of treatment effects are as accurate as possible and so that researchers can assess effects of the treatment scavenger and predator activity. Also, carcasses collected for residue analyses should be identified as belonging to victims.

If I received an efficacy report which described research which was curtailed prematurely, for whatever reason, I would have little uses for the document. A toxicant study curtailed at the first signs of symptoms would not tell me the most important things that I need to know: how many animals died and how many survived. I would have no choice but to reject such a study and suggest that the researcher do it right the next time.

What I have discussed thus far is so "common sense" that, until recently, there appeared to be no need to set a "standard" requiring that efficacy studies of vertebrate toxicants be continued until the subjects' ultimate fates (death or survival) were determined. As questions such as the ones before you have arisen in recent years, the subject of experimental endpoints will be addressed in the revised product performance guidelines for vertebrate pesticides. I am working on revising those guidelines at present.

All of this having been said, I should note that it would make sense to curtail an efficacy research study prematurely if poisoned subjects appeared to be in such conscious pain or other distress that it became clear that the poison was inappropriate for further development as a rodenticide.

University of California, Davis
Addendum to Annual Report of Research Facility

A. USDA Exceptions to Provisions of the Act:

1. The USDA Administrator granted an exception to the number of cesarean-sections that can be performed on normal, female nonhuman primates. This exception applied to 36 animals during the reporting period.

Justification for cesarean-sections:

Studies that focus on fetal inherited illnesses, other illnesses, and various corrective therapies for these illnesses, require that the animals be delivered by cesarean-section at a standardized time point. This is important for several reasons. First, the fetuses and newborns are valuable research animals from which substantial information can be obtained, and delivery by cesarean-section decreases the risk of parturition-related mortality. In addition, animals that deliver spontaneously typically do so over a large range of gestational ages, which makes it very difficult to accurately assess a number of significant normal developmental, physiological and behavioral milestones. Delivering the infant by cesarean-section is the best method for obtaining viable, healthy offspring without confounding variables.

Justification for multiple cesarean-sections in the same animal:

Multiple cesarean-sections are routinely performed on humans. Nonhuman primates that undergo comparable procedures at the [b2,b7f] rarely have post-surgical complications and, as borne out by numerous years of experience (>20 years), are fertile post-operatively. Any animal with prior evidence of complications is not included in this exception. Similar to humans, extensive years of experience indicate that post-operatively these animals do not exhibit any problems or ill health.

The practice has been to maintain a breeding colony of rhesus and long-tailed macaques at the [b2,b7f] that can provide the required number of pregnancies for research purposes. Using animals more than once reduces the number of animals that have to be imported. As an example, if 100 animals are used per year for these studies, and if these animals could not be returned to the breeding colony, it would be necessary to import additional animals to replace these animals. The net effect of using these animals only once would be that an increased number of nonhuman primates would be needed, and that many valuable, healthy research animals would be euthanized because of their surgical history. With multiple use, and using procedures routinely used in humans, these animals can remain productive for many years, thus reducing the number of animals overall that are needed. This exception allows for up to four cesarean-sections per animal.

2. The USDA Administrator granted an exemption to perform another major survival surgery on one nonhuman primate.

Justification for a second multiple major survival surgery in the same animal:

Two investigators, who work closely with each other, were trying to maximize the use of animals on their studies. One investigator had an animal that was highly trained in manual tasks and had already undergone three prior surgical procedures related to the approved protocol (cranial implant and eye coil replacement, repair of eye coil, removal of cranial implant). Another investigator requested that this animal be transferred to her IACUC-approved protocol, which focuses on evaluating the behavioral consequences of stroke and head injury in humans. Since not all animals can easily acquire complex skills, and this animal was already performing quite well, the IACUC requested an exemption to perform another major survival surgery on this animal. The procedure involved producing a lesion (1 mm x 2 mm) in area 5 of the neocortex. After recovery from the lesioning procedure, the animal was assessed for the effects of the lesion on reaching, grasping and bilateral coordination. The investigator is scheduled to perform a terminal procedure on this animal by December 8, 2006.

B. Water Regulation:

In studies involving 18 animals, the IACUC has granted exceptions to allow non-human primates to be maintained on regimens of water regulation. These are studies in which the animals receive water or other liquids as a reward for performing tasks. If the animals were allowed to satiate themselves with water outside of the study period, they would not be motivated to perform the tasks. The animals receive their necessary water during the day as they perform the tasks.

The IACUC and the [b2,b7f] have developed detailed guidelines to ensure that these animals receive adequate amounts of water during the day to support their health and well-being. In order to assure that only animals which are physiologically, as well as psychologically, capable of adapting to chronic water regulation are placed in these studies, all animals first undergo a careful screening process, which lasts approximately seven days. During this reporting period, a total of two animals were screened and were included in the 18 noted above.

During periods of water regulation, the animals are allotted carefully calculated amounts of water appropriate to their physiologic needs, and within the IACUC policy guidelines. Neither weight loss nor dehydration has been shown to result when these guidelines are followed. The animals are monitored very closely by veterinary staff and animal care staff when water regulation protocols are used.

C. Metabolism Cages > 12 hours

In studies involving 23 sheep, the IACUC has approved the use of metabolism cages for restraint periods greater than 12 hours.

One study involving 19 sheep evaluated a new sonomicrometer instrument which can measure, with precision, dynamic changes in the circumference and thickness of the airways as well as bronchial and circumflex bloodflow in chronic or anesthetized sheep. These animals are surgically

instrumented with electronic recording devices for up to 30 days. The extremely small wires from these devices are externalized through the skin. It is necessary to house the sheep in metabolism cages to prevent them from destroying the externalized portion of the devices. As part of the study, the sheep were routinely (2-3 times per week) exercised on a treadmill during the period of prolonged restraint.

Another study involving 4 sheep investigated the blood/surface interaction of a new polymer used to coat central venous catheters to extend the patency of the catheters. The sheep were kept in metabolism cages to prevent them from disturbing the exposed portion of the catheter.



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